28 PIERRE KÖENIG ST., TALPIOT INDUSTRIAL AREA
POB 53231 JERUSALEM 91531 ISRAEL
TEL. **972-2-6781861** FAX. **972-2-6781852**
e-mail: novamed@netvision.net.il

AUG 2 4 2000

510(k) Summary – K000718

1. Submitter: Novamed, Ltd., 28 Pierre Koenig Street, POB 53231 Jerusalem 91531 Israel. Phone: 972-2-6781861, Fax: 972-2-6781852, e-mail: novamed@netvision.net.il
Contact person: Gerald M. Slutzky, Ph.D., Director, Diagnostics Division

2. Name of device: *ChromoStreak Urine Culture Device*
Classification name: Microorganism differentiation and identification device
Common/usual name: Urine culture device
Proprietary name: *ChromoStreak*

Classification: According to FDA 91-4246 (*Classification Names for Medical Devices and In Vitro Diagnostic Products*), Microorganism differentiation and identification devices are classified in Class I. The appropriate regulation is 866.2660

3. Identification of the predicate device: conventional growth, isolation and identification of bacteria using agar filled Petri dishes and supplementary tests.

4. Description of the device: *ChromoStreak* comprises a plastic paddle with two types of agar attached back-to-back, housed in a closed transparent plastic tube. A ring with elongated prongs is attached to the end of the paddle so that there are prongs on each side of the slide. The ends of the prongs are dipped into the urine sample. Upon re-insertion into the plastic tube, the prongs are prevented from moving and the agar surfaces are inoculated with bacteria from the urine sample as the agar-coated paddle passes over the prongs. The result is a series of streaks of decreasing bacterial concentration that permits isolation of single colonies even when the original bacterial population of the sample was as high as 10^7 organisms per milliliter. The incorporation of **Uri*Select*®3** chromogenic agar allows (1) direct identification via demonstration of enzyme activities of the bacteria most often responsible for urinary tract infections, namely *E. coli*, Proteus, and group D streptococci; and (2) orientation for the diagnosis of the other urinary pathogens, in particular K.E.S. group enterobacteria (Klebsiella, Enterobacter, Serratia).

5. Intended use: the *ChromoStreak Urine Culture Device* is a specimen collection and transport media used for the isolation, enumeration, and presumptive identification of bacteria in urine.

6. Performance and design specifications: pathogenic bacteria found in urine samples at levels from 10^3 to 10^7 CFU/ml are detected accurately and consistently when using the *ChromoStreak Urine Culture Device*. Experimental evidence to support this claim is given in the application in the Precision Study. Following the instructions of the manufacturer of **Uri*Select*®3** agar (Sanofi Diagnostics Pasteur, Marnes les Coquettes, France) makes possible the presumptive identification of the common causative organisms of urinary tract infections (*E. coli*, Proteus and group D streptococci). Results of a clinical study that support this contention are give as part of this application.

7. Performance data: the pathogenic microorganisms found in 270 positive urine samples were identified by both *ChromoStreak* and API strips. *ChromoStreak* correctly identified 110 of 127 *E. coli* isolates (86.7%), 28 of 29 Proteus isolates (96.6%), 29 of 29 (100%) Enterococcus isolates and 44 of 48 (91.7%) K.E.S.C. isolates. Overall, 211 of 270 (78.1%) isolates were correctly identified.

8. User quality control: Quality control tests are performed on each lot of *ChromoStreak* at the time of manufacture. Product users who wish to perform their own quality control may use the following procedure.

One. Prepare a suspension (10^4-10^5 CFU/ml) of each of the following organisms in sterile urine. Confirm the exact organism concentration by inoculating 10 µl with a calibrated loop on reference plates of **Uri*Select*®3** and MacConkey agar.

Two. Test the suspension according to the *ChromoStreak* Instructions for Use.

TYPICAL CULTURE RESPONSE (after 24 hours at 37°C)

Strain	Growth rate	Colony Appearance	
		Uri*Select*®3	MacConkey
E. coli ATCC No. 25922	2-3 mm colonies can be seen within 12-14 hr	Purple	Red-purple colonies with smooth borders
S. aureus ATCC No. 25923	MacConkey-no growth **Uri*Select*®3** -1 mm colonies can be seen within 12-14 hr	White	No growth
E. faecalis ATCC No. 29212	MacConkey-minute colonies **Uri*Select*®3**-0.5-1 mm colonies can be seen within 16-20 hr	Bright frank blue	Red

If the device does not support the expected growth of organisms, it has deteriorated and should not be used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 4 2000

Gerald M. Slutzky, Ph.D.
Director, Research and Development
Novamed Ltd.
28 Pierre Köenig Street
Talpiot Industrial Area
PO Box 53231 Jerusalem 91531
Israel

Re: K000718
Trade Name: *ChromoStreak* Urine Culture Device
Regulatory Class: I
Product Code: JSN
Dated: July 24, 2000
Received: July 27, 2000

Dear Dr. Slutzky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K000718

Device Name: *ChromoStreak Urine Culture Device*

Indications for Use:

The Novamed, Ltd. ***ChromoStreak*** **Urine Culture Device** is used for the isolation, enumeration, and identification of bacteria in urine. A set of plastic prongs on the end of the device is dipped into the urine sample. The drops of urine that adhere to the prongs are then streaked across two different agar surfaces (**Uri***Select*®**3** agar on one side, MacConkey agar on the other). A dilution effect takes place which allows the isolation of single colonies. The incorporation of **Uri***Select*®**3** chromogenic agar allows (1) direct identification via demonstration of enzyme activities of the bacteria most often responsible for urinary tract infections, namely *E. coli*, Proteus, and group D streptococci; and (2) orientation for the diagnosis of the other urinary pathogens, in particular K.E.S. group enterobacteria (Klebsiella, Enterobacter, Serratia).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000718

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)